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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/575,945

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EXAMINER

ZALASKY, KATHERINE M

ART UNIT

PAPER NUMBER

4153

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/575,945	Applicant(s) BERGSTROM ET AL.	
	Examiner KATHERINE ZALASKY	Art Unit 4153	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18, 20-52, 54 and 55 is/are pending in the application.
- 4a) Of the above claim(s) 16-18, 20-52, 54 and 55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-18, 20-52, 54 and 55 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 April 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20060413, 20071220</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-15, drawn to a separation matrix.

Group II, claim(s) 16-18, drawn to a chromatography column.

Group III, claim(s) 20-31 and 46, drawn to an improvement to a method of providing a separation matrix and a separation matrix.

Group IV, claim(s) 32-45 and 54-55, drawn to a method of preparing a separation matrix and a separation matrix.

Group V, claim(s) 47-52, drawn to a process in liquid chromatography.

2. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

While Groups I-V share the special technical feature of a porous support with a ligand, where the ligands provide a chemical gradient in the support, the feature does not offer contribution over the prior art. Carlsson et al. (US 6,528,322) discloses a porous support (C5/L39-51) with ligands (C6/L5-7), where a variation in ligand density provides a chemical gradient on the support (C6/L19-22, 40-43).

3. During a telephone conversation with Yonggang Ji on September 8, 2008 a provisional election was made with traverse to prosecute the invention of **Group I**,

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claims 1-15. Affirmation of this election must be made by applicant in replying to this Office action. **Claims 16-18, 20-52, and 54-55** are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP

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§ 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Drawings

6. The drawings are objected to because:

- In Figure 1, it is not clear how the x-axis, the *radial coordinate*, has values up to 200 μm ; the description, on page 23, states that the *diameter* of the particle is 190 μm
- In Figures 7A-H, it is not clear how the radius can take on a negative value (radius ranges from 1 to -1 in the figure)

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering

of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

7. **Claims 2-15** are objected to because of the following:

- In **claims 2 and 11**, for claim language consistency, "the support" should be replaced with "the porous support"
- In **claim 2**, the recitation of "the ligand gradient(s)" renders the claim unclear because a ligand gradient is not recited prior to said limitation; suggested correction is to replace "the ligand gradient(s)" with "a ligand gradient" or define a ligand gradient earlier in the claim
- In **claims 3 and 8-10**, for claim language consistency, "one gradient" should be replaced with "one chemical gradient"
- In **claim 7**, for claim language consistency, "one or more gradient(s)" should be replaced with "one or more chemical gradient(s)"
- In **claim 7**, the recitation of "which matrix" is unclear; a suggested replacement is "wherein the matrix"

Appropriate correction is required.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. **Claims 1, 3-4 and 8-15** are rejected under 35 U.S.C. 102(b) as being anticipated by Carlsson et al. (US 6,528,322).

Regarding **claim 1**, Carlsson et al. discloses a separation matrix comprising a porous support (C5/L39-46, 60-62); and ligands coupled to the surfaces of said porous support (C6/L5-7, 19-22), wherein the ligands provide at least one chemical gradient in the support (C6/L40-43, ligand density gradient).

Regarding **claims 3-4 and 8-10**, Carlsson et al. discloses all of the claim limitations as set forth above. Additionally, Carlsson et al. discloses the separation matrix wherein:

- at least one gradient is a ligand density gradient formed by a changing density of ligands on the support (C6/L40-43)
- two or more chemical gradients are present in the support and at least one gradient is a ligand density gradient (C6/L40-43, ligand density gradient, and C5/L62-C6/L4, separation zone has two or more subzones with different ligand functionalities)
- at least one gradient is the result of varying pKa values of functional groups of the ligands present on the support (C5/L62-C6/L4, separation

zone has two or more subzones with different ligand functionalities, each different ligand has a different pKa value)

- at least one gradient is the result of a varying net charge of the ligands present on the support (C6/L63-66, stepwise or continuously changed ion-strength)
- at least one gradient is a continuous and smooth gradient (C6/L63-66, stepwise or continuously changed ion-strength, and C7/L8-24, continuous lines or bands of reagent)

Regarding **claims 11-15**, Carlsson et al. discloses all of the claim limitations as set forth above. Additionally, Carlsson et al. discloses the separation matrix wherein:

- the ligands present on the support provide at least two different functionalities (C5/L62-C6/L16, separation zone has two or more subzones with different ligand functionalities)
- said functionalities are selected from the group consisting of cation exchange ligands, anion exchange ligands, hydrophobic interaction chromatography (HIC) ligands, reversed phase chromatography (RPC) ligands, immobilized metal chelating ligands (IMAC), thiophilic ligands, and affinity ligands (C5/L62-C6/L16)
- said at least two different functionalities are present on the same ligand (C5/L62-C6/L16, amphoteric and aphiphilic ligands may be used)
- the ligands present zwitterionic functionalities (C5/L62-C6/L16, amphoteric ligand may be used)

- said at least two different functionalities are present on different ligand kinds, and each such ligand kind provides a separate chemical gradient within the support (C5/L62-C6/L16, separation zone has two or more subzones with different ligand functionalities)

10. **Claims 1-3 and 5-7** are rejected under 35 U.S.C. 102(b) as being anticipated by Velander et al (US 5,977,345).

Regarding **claim 1**, Velander et al. discloses a separation matrix comprising a porous support (C10/L25-31); and ligands coupled to the surfaces of said porous support (abstract), wherein the ligands provide at least one chemical gradient in the support (abstract, gradient from inside the particle to outside the particle of the support).

Regarding **claim 2**, Velander et al. discloses all of the claim limitations as set forth above. Additionally, Velander et al. discloses the separation matrix wherein the support comprises porous particles (C10/L25-31) and the ligand gradient(s) extend between the center and the exterior surface of each porous particle (abstract).

Regarding **claim 3**, Velander et al. discloses all of the claim limitations as set forth above. Additionally, Velander et al. discloses the separation matrix wherein at least one gradient is a ligand density gradient formed by a changing density of ligands on the support (abstract, gradient from the interior of the particle to the exterior of the particles of the support)

Regarding **claims 5-6**, Velander et al. discloses all of the claim limitations as set forth above. Additionally, Velander et al. discloses the separation matrix wherein:

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- in the ligand density gradient(s), the ligand concentration increases towards the center of the support (abstract, the concentration is highest at the center of the particles and decreases toward the exterior the particles of the support)
- in the ligand density gradient(s), the ligand concentration decreases towards the center of the support (C2/L54-59, the concentration is highest on the exterior of the particles and decreases toward the interior of the particles of the support)

Regarding **claim 7**, Velandar et al. discloses all of the claim limitations as set forth above. Additionally, Velandar et al. discloses the separation matrix, which matrix is a chromatography matrix (C17/L33-35) comprised of a plurality of essentially spherical particles (C10/L25-31), wherein each particle presents one or more gradient(s) perpendicular to the direction of the liquid flow applied in chromatography (abstract, ligand density gradient on each spherical particle; therefore, the density gradient will extend radially from the particle center and at least one gradient will exist perpendicular to an applied liquid flow).

Regarding limitations recited in **claim 7** which are directed to a manner of using the separation matrix, such as applying a flow of liquid in chromatography, it is noted that neither the manner of operating a disclosed device nor material or article worked upon further limit an apparatus claim. Said limitations do not differentiate apparatus claims from prior art. See MPEP § 2114 and 2115. Further, it has been held that process limitations do not have patentable weight in an apparatus claim. See Ex parte

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Thibault, 164 USPQ 666, 667 (Bd. App. 1969) that states "Expressions relating the apparatus to contents thereof and to an intended operation are of no significance in determining patentability of the apparatus claim."

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE ZALASKY whose telephone number is (571)270-7064. The examiner can normally be reached on Monday-Thursday, 7:30am - 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Basia Ridley can be reached on (571) 272-1453. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KZ

11 September 2008

/Basia Ridley/
Supervisory Patent Examiner, Art Unit 4153